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Ad Hoc Committee on an International Convention against the Reproductive Cloning of Human Beings
25 February-1 March 2002

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A. Introduction

1. The General Assembly, in its resolution 56/93 of 12 December 2001, decided to establish the Ad Hoc Committee on an International Convention against the Reproductive Cloning of Human Beings, and also decided that the Ad Hoc Committee would meet from 25 February to 1 March 2002 to consider the elaboration of a mandate for the negotiation of such an international convention, including a list of the existing international instruments to be taken into consideration and a list of issues to be addressed in the convention.

2. Pursuant to that resolution, the present document, in section B, contains a list of international instruments, adopted at both global and regional levels, prepared by the Secretariat for the convenience of delegations. While no attempt has been made to provide an exhaustive listing of all instruments, the list includes legal and other instruments containing norms and guidelines pertaining to the reproductive cloning of human beings.

3. In addition, a list of selected international instruments dealing with other relevant or related issues, such as the rights of the individual, biotechnology and medical and scientific research, is presented in section C also for the information of delegations. The list includes documents developed by international professional associations.

4. Annex I to the present document contains selected excerpts from the listed instruments, arranged by topic, and is intended to be without prejudice to the eventual inclusion of any particular topic or issue in the list of issues to be addressed in the convention.

5. Annex II contains, also for the benefit of delegations, a further list of selected key reports on the question of human reproductive cloning and bioethics, prepared either under the auspices of various United Nations bodies and specialized agencies, or by regional intergovernmental organizations.

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B. Selected international instruments concerning the reproductive cloning of human beings

Global instruments

United Nations Educational, Scientific and Cultural Organization

- Universal Declaration on the Human Genome and Human Rights, 11 November 1997

United Nations General Assembly

- Resolution 53/152 on the human genome and human rights, 9 December 1998

United Nations Commission on Human Rights

- Resolution 2001/71 on human rights and bioethics, 25 April 2001
- Resolution 1999/63 on human rights and bioethics, 28 April 1999
- Resolution 1997/71 on human rights and bioethics, 16 April 1997
- Resolution 1995/82 on human rights and bioethics, 8 March 1995
- Resolution 1993/91 on human rights and bioethics, 10 March 1993

World Health Organization

- Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, 16 May 1998
- Resolution WHA 50.37 on cloning in human reproduction, 14 May 1997

Regional instruments and documents

Council of Europe

- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, 4 April 1997
- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, 12 January 1998
- Council of Europe, Parliamentary Assembly, Order No. 534 (1997) on research and the cloning of human beings, 23 September 1997
- Council of Europe, Parliamentary Assembly, Opinion No. 202 (1997) on the draft additional protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings, 23 September 1997
- Council of Europe, Parliamentary Assembly, Recommendation 1046 (1986) on the use of human embryos and fetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, 24 September 1986
- Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, 2 February 1989

European Union

- Charter of Fundamental Rights of the European Union, 7 December 2000
- European Council, Declaration on Banning the Cloning of Human Beings, 16 June 1997
- European Parliament, Resolution on human cloning, 7 September 2000
- European Parliament, Resolution on human cloning, 15 January 1998
- European Parliament, Resolution on Cloning, 12 March 1997
- European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989

Organization of African Unity

- Resolution on bioethics, 32nd Assembly of OAU Heads of State and Government, 10 July 1996

Group of Eight

- Communiqué, Denver Summit of the Eight, 22 June 1997

C. Other instruments dealing with related issues

United Nations Environment Programme

- Convention on Biological Diversity, 1992

United Nations General Assembly

- Universal Declaration of Human Rights, 1948
- International Covenant on Civil and Political Rights, 1966

World Trade Organization (WTO)

- Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), 15 April 1994

Council of Europe

- Council of Europe, Parliamentary Assembly, Recommendation 1468 (2000) on biotechnologies, 29 June 2000
- Council of Europe, Parliamentary Assembly, Recommendation 1425 (1999) on biotechnology and intellectual property, 23 September 1999

European Union

- Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, 6 July 1998

European Patent Office (EPO)

- European Patent Convention, 1973

Group of Eight (G-8)

- G-8 Communiqué, Kyushu-Okinawa Summit 2000, 23 July 2000

Relevant documents prepared by international professional associations

World Medical Association (WMA)

- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, June 1964
- Resolution on cloning, adopted by the 147th Council Session of the World Medical Association, Paris, May 1997, and endorsed by the 49th WMA General Assembly, Hamburg, Germany, November 1997

Annex I

Selected excerpts arranged by topic

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Instrument		*Excerpts*
1. General provisions		
(a) Global instruments		
(i) United Nations General Assembly		
Resolution 53/152 on the human genome and human rights, 9 December 1998	*Third preambular para.*	*Recalling also* that, in accordance with the Universal Declaration of Human Rights, recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world
	Fourth preambular para.	*Aware* of the rapid development of the life sciences and of ethical concerns raised by certain of their applications with regard to the dignity of the human race and the rights and freedoms of the individual,
	Fifth preambular para.	*Seeking* to promote scientific and technical progress in the fields of biology and genetics in a manner respectful of fundamental rights and for the benefit of all,
	Single operative para.	*Endorses* the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997;
(ii) World Health Organization (WHO)		
a. Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, 16 May 1998	*First preambular para.*	Recalling resolution WHA 50.37 and its condemnation of human cloning for reproductive purposes as contrary to human dignity;
	Second preambular para.	Noting the general consensus reached at the national and international levels since the Fifth World Health Assembly regarding human cloning for reproductive purposes;
	Third preambular para.	Noting in particular UNESCO's Universal Declaration on the Human Genome and Human Rights and the Council of Europe's Additional Protocol to the Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, which deal with the prohibition of cloning of human beings;
	Fourth preambular para.	Considering that the currently available information from animal studies involving cloning by somatic cell nuclear transfer indicates that this would be an unsafe procedure for reproductive purposes in the human;
	Fifth preambular para.	Recognizing that developments in cloning have unprecedented ethical implications and raise serious matters for concern in terms of safety of the individual and subsequent generations of human beings,
	Para. 1	Reaffirms that cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and integrity;
b. Resolution WHA 50.37 on cloning in human reproduction, 14 May 1997	*Para. 1*	*Affirms* that the use of cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and morality;

Instrument		*Excerpts*
(b) Regional instruments and documents		
(i) Council of Europe		
a. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, of 4 April 1997. (Convention on Human Rights and Biomedicine) (Council of Europe document DIR/JUR(96)14, European Treaty Series No. 164)	*Article 2*	The interests and welfare of the human being shall prevail over the sole interest of society or science.
b. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, 12 January 1998 (European Treaty Series No. 168).	*First preambular para.*	Noting scientific developments in the field of mammal cloning, particularly through embryo splitting and nuclear transfer;
	Fifth preambular para.	Considering however that the instrumentalization of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine;
	Sixth preambular para.	Considering also the serious difficulties of a medical, psychological and social nature that such a deliberate biomedical practice might imply for all the individuals involved;
(ii) European Union (EU)		
a. Charter of Fundamental Rights of the European Union, adopted at Nice, France, 7 December 2000 (2000 O.J. (C 364) 01).	*Article 1*	Human dignity is inviolable. It must be respected and protected.
	Article 3 (1)	Everyone has the right to respect for his or her physical and mental integrity.
b. European Council, Declaration on Banning the Cloning of Human Beings, 16 June 1997 (*Bulletin of the European Union* 6-1997, Annexes to the Proceedings of the Presidency, 7/7)	*Para. 1*	[The] European Council notes that the growth of new technologies in the area of genetic engineering poses acute ethical problems.
c. European Parliament, Resolution on human cloning, 7 September 2000 (*Bulletin of the European Union* 9-2000, Human Rights, 5/12)	*Preambular para. F*	... there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against *ordre public* and morality,
d. European Parliament, Resolution on human cloning, 15 January 1998 (1998 O.J. (C 34) 164 (15 January 1998))	*Preambular para. C*	... the cloning of human beings, whether carried out on an experimental basis, in the context of fertility treatments, pre-implantation diagnosis, for tissue transplantation or for any other purpose whatsoever, is unethical, morally repugnant, contrary to respect for the person and a grave violation of fundamental human rights which cannot under any circumstance be justified or accepted,

Instrument		*Excerpts*
	Para. 1	Reiterates that every individual has the right to his own genetic identity and that human cloning must be prohibited;
e. European Parliament, Resolution on cloning, 12 March 1997 (1997 O.J. (C 115) 14.4/92 (12 March 1997))	*Preambular para. A*	... cloning breaks new ethical ground and has led to great public concern,
	Preambular para. B	... the cloning of human beings, whether experimentally, in the context of fertility treatment, pre-implantation diagnosis, tissue transplantation or for any other purpose whatsoever, cannot under any circumstances be justified or tolerated by any society, because it is a serious violation of fundamental human rights and is contrary to the principle of equality of human beings as it permits a eugenic and racist selection of the human race, it offends against human dignity and it requires experimentation on humans,
	Preambular para. 1	Stresses that each individual has a right to his or her own genetic identity and that human cloning is, and must continue to be, prohibited;
f. European Parliament, resolution on the ethical and legal problems of genetic engineering, 17 March 1989 (*Official Journal* C 96, 17 April 1989, pp. 165-171)	*Preambular para. D*	... genome analysis may, on the one hand, bring about possible improvements in diagnostics, preventive medicine and therapy, but on the other, entails the risk of creating compulsory eugenic and preventive objectives, of applying genetic analysis for the purpose of social control and the segregation of whole social strata, of selecting embryos and fetuses on the basis of their genetic characteristics alone and of producing fundamental changes in our society,
	Para. 29	Considers that the legal status of the human embryo must be defined to provide unequivocal protection of genetic identity;
	Para. 30	Considers that even [if] a recombination of genes only partly alters the genotype, the identity of the individual is falsified, which is both irresponsible and unjustifiable because a very individual legal asset is involved;
(iii) Organization of African Unity (OAU)		
Resolution on bioethics, 32nd Assembly of OAU Heads of State and Government, 10 July 1996 (AHG/Res. 254 (XXXII))	*Fifth preambular para.*	*Recognizing* the rapid progress achieved in the area of life sciences, and the dangers which could be posed to the dignity and integrity of the individual by certain practices;
	Para. 3	*Pledges* to promote within the continent the following universal rights and principles under conditions of respect for cultural, social and religious values:
		...
		(b) Inviolability of the human body and of the genetic heritage of the human species,
		(c) Inalienability of the person, which prohibits the subjection of the human body, its components, particularly the human genes and the sequences thereof, to commercial and property rights purposes,
		...

Instrument		*Excerpts*
		(f) Supervision of research facilities on embryos, especially those produced as a result of medical procedures offering assistance towards procreation, and the attendant application of such procedures, so as to obviate selective eugenic by-products, particularly those relating to sex considerations,
(c) Other instruments dealing with related issues		
(i) United Nations Environment Programme (UNEP)		
Convention on Biological Diversity, 1992 (United Nations, *Treaty Series*, vol. 1760, No. 30619, p. 79)	*Article 15 (1)*	Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national Governments and is subject to national legislation.
(ii) United Nations General Assembly		
Universal Declaration of Human Rights, 1948 (resolution 217 A (III) of 10 December 1948)	*Article 1*	All human beings are born free and equal in dignity and rights ...
2. Definitions		
(a) Regional instruments and documents		
(i) Council of Europe		
a. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, of 12 January 1998 (European Treaty Series No. 168).	*Article 1*	1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited; 2. For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set.
b. Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, of 2 February 1989, adopted by the Assembly, 40th Ordinary Session, 3rd Part, 30 January-3 February 1989	*Appendix, para. 25*	"[V]iable" embryos shall be understood to mean embryos which are free of biological characteristics likely to prevent their development; however the non-viability of human embryos and fetuses shall be determined solely by objective biological criteria based on the embryo's intrinsic defects.
(ii) European Union (EU)		
a. European Parliament resolution on human cloning, of 7 September 2000 (*Bulletin of the European Union* 9-2000, Human Rights, 5/12)	*Para. 1*	[P]arliament defines human cloning as the creation of embryos having the same genetic make-up as another human being, dead or alive, at any stage of their development, without any possible distinction as regards the method used,
b. European Parliament, resolution on human cloning, of 15 January 1998 (1998 O.J. (C 34) 164 (15 January 1998))	*Para. B*	[H]uman cloning is defined as the creation of human embryos having the same genetic make-up as another human being, dead or alive, at any stage of its development from the moment of fertilization, without any possible distinction as regards the method used,

Instrument		*Excerpts*
(b) Other instruments dealing with related issues		
United Nations Environment Programme (UNEP)		
Convention on Biological Diversity, of 1992 (United Nations, *Treaty Series*, vol. 1760, No. 30619, p. 79)	*Article 2*	"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity. "Genetic resources" means genetic material of actual or potential value.
3. Reporting/monitoring mechanisms		
(a) Global instruments		
(i) United Nations Commission on Human Rights		
a. Resolution 2001/71 on human rights and bioethics, 25 April 2001	*Para. 4*	*Invites* the Secretary-General ... to consider establishing a working group of independent experts from, inter alia, the United Nations Educational, Scientific and Cultural Organization, the World Health Organization and the World Intellectual Property Organization, which would reflect, in particular, on the possible follow-up to the Universal Declaration on the Human Genome and Human Rights and report to the Secretary-General within a period to be determined by him;
	Para. 7	*Invites* Governments to consider establishing independent, multidisciplinary and pluralist committees of ethics to assess, notably in conjunction with the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization, the ethical, social and human questions raised by the biomedical research undergone by human beings and, in particular, research relating to the human genome and its applications, and also invites them to inform the Secretary-General of the establishment of any such bodies, with a view to promoting exchanges of experience between such institutions;
b. Resolution 1999/63 on human rights and bioethics, 28 April 1999	*Para. 2*	*Invites* the United Nations Educational, Scientific and Cultural Organization, the World Health Organization, the Office of the [United Nations] High Commissioner for Human Rights, and the other United Nations bodies and specialized agencies concerned to report to the Secretary-General on the activities conducted in their respective areas to ensure that the principles set forth in the Universal Declaration on the Human Genome and Human Rights are taken into account;
	...	...
	Para. 6	*Invites* Governments to consider establishing independent, multidisciplinary and pluralist committees of ethics to assess, notably in conjunction with the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization, the ethical, social and human questions raised by the biomedical research undergone by human beings and, in particular, research relating to the human genome and

Instrument		*Excerpts*
		its applications, and also invites them to inform the Secretary-General of the establishment of any such bodies, with a view to promoting exchanges of experience between such institutions;
c. Resolution 1997/71 on human rights and bioethics, 16 April 1997	*Para. 2*	*Invites* Governments, the specialized agencies and other organizations of the United Nations system, in particular the United Nations Educational, Scientific and Cultural Organization and the World Health Organization, and other intergovernmental, particularly regional, organizations and non-governmental organizations to inform the Secretary-General of activities being carried out to ensure that the life sciences develop in a manner respectful of human rights and beneficial to humanity as a whole;
	Para. 5	*Invites* Governments to consider establishing independent, multidisciplinary and pluralist committees of ethics to assess, notably in conjunction with the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization, the ethical, social and human questions raised by the biomedical research undergone by human beings and, in particular, research relating to the human genome and its applications, and also invites them to inform the Secretary-General of the establishment of any such bodies, with a view to promoting exchanges of experience between such institutions;
d. Resolution 1995/82 on human rights and bioethics, 8 March 1995	*Para. 2*	*Invites* Governments, the specialized agencies and other organizations of the United Nations system, in particular the United Nations Educational, Scientific and Cultural Organization and the World Health Organization, and other intergovernmental, particularly regional, organizations and non-governmental organizations to inform the Secretary-General of activities being carried out to ensure that the life sciences develop in a manner respectful of human rights and beneficial to humanity as a whole;
	Para. 3	*Invites* States to inform the Secretary-General of legislative or other measures taken to this effect, including the possible establishment of national consultative bodies, with a view to promoting exchanges of experience between such institutions;
e. Resolution 1993/91 on human rights and bioethics, 10 March 1993	*Para. 1*	*Invites* Governments, the specialized agencies and other organizations of the United Nations system, in particular the United Nations Educational, Scientific and Cultural Organization and the World Health Organization, and other intergovernmental, particularly regional, organizations and non-governmental organizations to inform the Secretary-General of activities being carried out to ensure that the life sciences develop in a manner respectful of human rights;
	Para. 2	*Invites* States to inform the Secretary-General of legislative or other measures taken to this effect, including the possible establishment of national consultative bodies, with a view to promoting exchanges of experience between such institutions;

Instrument		*Excerpts*
(ii) World Health Organization (WHO)		
a. Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, 16 May 1998	*Para. 3*	*Requests* the Director: (1) To establish a group, involving also government experts, with the aim of clarifying concepts and developing guidelines relating to the use of cloning procedures for non-reproductive purposes; (2) To continue to monitor, assess and clarify, in consultation with other international organizations, national governments and professional and scientific bodies, the ethical, scientific, social and legal implications of the use of cloning for human health; ...
b. Resolution WHA 50.37 on cloning in human reproduction, 14 May 1997	*Fifth preambular para.*	Recognizing that developments in cloning and other genetic procedures have unprecedented ethical implications, and considering that related research and development should therefore be carefully monitored and assessed, and the rights and dignity of patients respected,
(b) Regional instruments and documents		
(i) Council of Europe		
a. Council of Europe, Parliamentary Assembly, Opinion No. 202 (1997) on the draft additional protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings, 23 September 1997, adopted by the Assembly, 1997 Ordinary Session, 4th Part, 22-26 September 1997	*Para. 8*	... the Assembly recommends that the Committee of Ministers: ... vi. Encourage member States to improve and increase information and education on biotechnological research related to human beings with a view to enhancing public support for the principles contained in the Convention on Human Rights and Biomedicine and its additional protocols;
b. Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, 2 February 1989, adopted by the Assembly, 40th Ordinary Session, 3rd Part, 30 January-3 February 1989	*Para. 9.B*	Recommends that the Committee of Ministers: ... Invite the Governments of member States: (i) To set up as a matter of urgency ... national or regional multidisciplinary bodies ...
	Para. 9.D	Recommends that the Committee of Ministers: ... Establish as a matter of urgency, as a safeguard, an international multidisciplinary body to ensure convergent approaches by the national bodies already operating or to be set up in accordance with subparagraph 9.B (i) above, and to avoid thereby the creation of "genetic havens".
c. Council of Europe, Parliamentary Assembly, Recommendation 1046 (1986) on the use of human embryos and fetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, 24 September 1986, adopted by the Assembly, 38th Ordinary Session, 2nd Part, 17-25 September 1986	*Para. 14.A*	Recommends that the Committee of Ministers: Call on the Governments of the member States: ... vi. To create national registers of accredited medical centres authorized to carry out such techniques and to make use of them for scientific purposes;

Instrument		*Excerpts*
(ii) European Union (EU)		
a. European Parliament, Resolution on cloning, 12 March 1997 (1997 O.J. (C 115) 14.4/92 (12 March 1997))	*Para. 9*	Calls for the establishment of a European Union Ethics Committee to assess ethical aspects of applications of gene technology and to monitor developments in this field ...;
b. European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989 (Official Journal C 96, 17/04/1989 pp. 165-171)	*Para. 11*	Sees the role of ethical committees and professional regulatory bodies solely as translating into practice the rules laid down by legislation;
(c) Other instruments dealing with related issues		
Council of Europe		
a. Council of Europe, Parliamentary Assembly, recommendation 1468 (2000) on Biotechnologies, 29 June 2000 (Gazette — Parliamentary Assembly — June 2000, No. IV/2000 (2000))	*Para. 6 (iii)*	... to prepare, in cooperation with other relevant organizations, for the introduction of an assessment method for ascertaining whether new technologies in medicine and biology are compatible with fundamental ethical principles, human rights and human dignity. This should take into account the decision-making procedures of individual countries and relevant international organizations as well as the different cultural, religious or social traditions or conventions in the member States ...
b. Council of Europe, Parliamentary Assembly, Recommendation 1425 (1999) on biotechnology and intellectual property, 23 September 1999 (*Official Gazette* — Parliamentary Assembly — September 1999, No. VI/99 (1999))	*Para. 13*	... the Assembly recommends that the Committee of Ministers, in cooperation with the European Union, the World Intellectual Property Organization, the Food and Agriculture Organization of the United Nations, the World Trade Organization, the United Nations Educational, Scientific and Cultural Organization, and in accordance with the Convention on Biological Diversity: (i) Study in detail all aspects linked to the protection of intellectual property in biotechnological innovations with a view to further improving international legislation in this field; ... (iii) Develop a code of conduct for scientists and scientific units working in the field of biotechnology which guarantees both free scientific access to worldwide genetic resources and benefit-sharing with developing countries; (iv) Discuss a suitable alternative system of protecting intellectual property in the field of biotechnology ...

Instrument		*Excerpts*
4. International cooperation		
(a) Global instruments		
(i) United Nations Educational, Scientific and Cultural Organization (UNESCO)		
Universal Declaration on the Human Genome and Human Rights, 11 November 1997	*Article 11*	Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to cooperate in identifying such practices and in taking, at the national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.
	Article 18	States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural cooperation, particularly between industrialized and developing countries.
(ii) World Health Organization (WHO)		
Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, of 16 May 1998	*Para. 3*	*Requests* the Director-General: ... (3) To ensure that member States are kept informed of developments in [the] area in order to facilitate decisions on national regulatory frameworks;
(b) Regional instruments and documents		
(i) European Union (EU)		
European Parliament Resolution on human cloning, 7 September 2000 (*Bulletin of the European Union* 9-2000, Human Rights, 5/12)	*Para. 5*	Urges maximum political, legislative, scientific and economic efforts to be aimed at therapies that use stem cells taken from adult subjects;
(ii) Group of Eight (G-8)		
Communiqué, Denver Summit of the Eight, 22 June 1997	*Para. 47*	... need for appropriate domestic measures and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child.
(c) Other instruments dealing with related issues		
United Nations Environment Programme (UNEP)		
Convention on Biological Diversity, of 1992 (United Nations, *Treaty Series*, No. 30619, vol. 1760, p. 79)	*Article 16 (1)*	Each Contracting Party, recognizing that technology includes biotechnology, ... undertakes, subject to the provisions of this article, to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that ... make use of genetic resources and do not cause significant damage to the environment.

Instrument		*Excerpts*
5. Prohibition/sanctions		
(a) Global instruments		
World Health Organization (WHO)		
Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, 16 May 1998	*Para. 2*	*Urges* member States to foster continued and informed debate on these issues and to take appropriate steps, including legal and judicial measures, to prohibit cloning for the purpose of replicating human individuals;
(b) Regional instruments and documents		
(i) Council of Europe		
a. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, of 4 April 1997 (Convention on Human Rights and Biomedicine) (Council of Europe document DIR/JUR(96)14, European Treaty Series No. 164)	*Article 12*	Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.
	Article 13	An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.
	Article 18	...
		2. The creation of human embryos for research purposes is prohibited.
	Article 27	None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention.
b. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, of 12 January 1998 (European Treaty Series No. 168)	*Article 1*	1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited;
		2. For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set.
c. Council of Europe, Parliamentary Assembly, Order No. 534 (1997) on research and the cloning of human beings, of 23 September 1997, adopted by the Assembly, 1997 Ordinary Session, Fourth Part, 22-26 September 1997	*Para. 2*	The Assembly, in its Opinion No. 202 (1997), has supported the principle that any intervention seeking to create a human being genetically identical to another human being, whether living or dead ("genetically identical human beings" meaning "human beings sharing the same nuclear gene set"), should be prohibited.
	Para. 3	The Assembly and the European Parliament have also called for an explicit worldwide ban on the cloning of human beings.

Instrument		*Excerpts*
d. Council of Europe, Parliamentary Assembly, Opinion No. 202 (1997) on the draft additional protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings, 23 September 1997, adopted by the Assembly, 1997 Ordinary Session, 4th Part, 22-26 September 1997	*Para. 8*	... the Assembly recommends that the Committee of Ministers: ... iv. Call on Governments of Council of Europe member and observer States, in line with the provisions of the draft additional protocol on the prohibition of cloning human beings, to create and implement legislation that bans any intervention seeking to create a human being genetically identical to another human being, whether living or dead ("genetically identical human beings" meaning "human beings sharing the same nuclear gene set"), and to provide for severe penal sanctions to deal with any violation. The parties should, however, guarantee the protection of human beings resulting from genetic interventions, albeit prohibited under the additional protocol to the Convention on Human Rights and Biomedicine; v. Ask the United Nations General Assembly to adopt provisions for an explicit worldwide ban on the cloning of human beings, seeking inspiration from the Council of Europe's additional protocol on the prohibition of cloning human beings;
e. Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, 2 February 1989, adopted by the Assembly, 40th Ordinary Session, 3rd Part, 30 January-3 February 1989	*Para. 9.A*	Recommends that the Committee of Ministers: Provide a framework of principles from which national laws or regulations can be developed in as universal and uniform a manner as possible, as proposed by its Recommendations 934 (1982) and 1046 (1986) as well as by this recommendation and its appendix;
	Appendix, para. 7	Embryos at the pre-implantation stage which have been expelled spontaneously from the uterus shall in no circumstances be re-transferred back.
	Appendix, para. 9	The removal of cells, tissues or embryonic or fetal organs, or the placenta or membranes, if live, for investigations other than of a diagnostic character and for preventive or therapeutic purposes shall be prohibited.
	Appendix, para. 11	Persons removing embryos or fetuses or parts therefrom from the uterus without clinical or legal justification or without the prior consent of the pregnant woman and, where appropriate, of her husband or partner in a stable relationship, and persons using such embryological materials in breach of the relevant legislation or regulations shall be duly penalized.
	Appendix, para. 16	The use of biological matter from dead embryos or fetuses for scientific, preventive, diagnostic, therapeutic, pharmaceutical, clinical or surgical purposes shall be permitted within the framework of the rules governing investigation, experimentation, diagnosis and therapy, in accordance with the terms of this recommendation.

Instrument		*Excerpts*
f. Council of Europe, Parliamentary Assembly, Recommendation 1046 (1986) on the use of human embryos and fetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, 24 September 1986, adopted by the Assembly, 38th Ordinary Session, 2nd Part, 17-25 September 1986	*Para. 14.A*	Recommends that the Committee of Ministers: Call on the Governments of the member States: ... ii. To limit the use of human embryos and fetuses and materials and tissues therefrom in an industrial context to purposes which are strictly therapeutic and for which no other means exist, according to the principles set out in the appendix, and to bring their legislation in line with these principles or to enact rules in accordance therewith which should, inter alia, specify the conditions in which removal and use may be undertaken for a diagnostic or therapeutic purpose; ... iv. To forbid anything that could be considered as undesirable use or deviations of these techniques, including: – The creation of identical human beings by cloning or any other method, whether for race selection purposes or not; – The implantation of a human embryo in the uterus of another animal or the reverse; – The fusion of human gametes with those of another animal ... – The creation of embryos from the sperm of different individuals; – The fusion of embryos or any other operation which might produce chimeras; – Ectogenesis, or the production of an individual and autonomous human being outside the uterus of a female, that is, in a laboratory; – The creation of children from people of the same sex; – Choice of sex by genetic manipulation for non-therapeutic purposes; – The creation of identical twins; – Research on viable human embryos; – Experimentation on living human embryos, whether viable or not; – The maintenance of embryos in vitro beyond the fourteenth day after fertilization (having deducted any time necessary for freezing); v. To provide appropriate sanctions to ensure the application of the rules enacted pursuant to this recommendation;

Instrument		*Excerpts*
(ii) European Union (EU)		
a. Charter of Fundamental Rights of the European Union, adopted at Nice, France, 7 December 2000 (2000 O.J. (C 364) 01).	*Article 3 (2)*	In the fields of medicine and biology, the following must be respected in particular: ... – The prohibition of eugenic practices, in particular those aiming at the selection of persons; – The prohibition on making the human body and its parts as such a source of financial gain; – The prohibition of the reproductive cloning of human beings.
b. European Council, Declaration on Banning the Cloning of Human Beings, June 1997 (*Bulletin of the European Union* 6-1997, Annexes to the Proceedings of the Presidency, 7/7)	*Para. 3*	Considering in particular that the protection of the human being and respect for the integrity of the human being are essential principles to which no exception can be made, the European Council invites the Council and the Commission, when defining Community policies, in particular on research and intellectual property, and when implementing existing programmes, to consider how human cloning may be prevented ...
	Para. 4	The European Council also stresses the determination of the member States, for their part, to take all measures necessary to prohibit human cloning.
c. European Parliament, Resolution on human cloning, 7 September 2000 (*Bulletin of the European Union* 9-2000, Human Rights, 5/12)	*Para. 4*	Repeats its call to each member State to enact binding legislation prohibiting all research into any kind of human cloning within its territory and providing for criminal penalties for any breach;
	Para. 8	Calls on the appropriate national and Community authorities to ensure that the ban on patenting or cloning human beings is reaffirmed and to adopt rules to this end;
	Para. 9	... the best way to implement this decision is to ensure that no research institution that is in any way involved in the cloning of human embryos gets money from the EU budget for any of their work;
	Para. 10	Repeats its insistence that there should be a universal and specific ban at the level of the United Nations on the cloning of human beings at all stages of formation and development;
d. European Parliament, Resolution on human cloning, 15 January 1998 (1998 O.J. (C 34) 164 (15 January 1998))	*Para. 1*	Reiterates that every individual has the right to his own genetic identity and that human cloning must be prohibited;
	Para. 3	Calls on each member State to enact binding legislation prohibiting all research on human cloning within its territory and providing for criminal sanctions for any breach;
	Para. 4	Calls on member States, the European Union and the United Nations to take all the steps necessary to bring about a universal and specific ban, which is legally binding, on the cloning of human beings, including the convening of a world conference on this subject;

Instrument		*Excerpts*
	Para. 6	Reminds the Council of Parliament's insistence that no Community funds should be used, directly or indirectly, for research programmes which make use of human cloning, and calls for confirmation that this prohibition is being fully applied;
e. European Parliament, Resolution on cloning, of 12 March 1997 (1997 O.J. (C 115) 14.4/92 (12 March 1997))	*Para. 1*	Stresses that each individual has a right to his or her own genetic identity and that human cloning is, and must continue to be, prohibited;
	Para. 2	Calls for an explicit worldwide ban on the cloning of human beings;
	Para. 3	Urges the member States to ban the cloning of human beings at all stages of formation and development, regardless of the method used, and to provide for penal sanctions to deal with any violation;
f. European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989 (*Official Journal* C 96, 17/04/1989 pp. 165-171)	*Para. 27*	Calls for an absolute ban on all experiments designed to reorganize on an arbitrary basis the genetic make-up of humans;
	Para. 28	Calls for legislation prohibiting any gene transfer to human germ line cells;
	Para. 38	Insists that any commercial or industrial use of embryos or fetuses, whether it involves the production of in vitro fertilized embryos for such purposes or imports of embryos or fetuses from third countries, must be a criminal offence;
	Para. 40	Calls for trade in frozen embryos for scientific, industrial or commercial purposes to be prohibited and made a criminal offence;
	Para. 41	Considers that the only possible response to the possibility of producing humans by cloning and to experiments with a view to the cloning of humans must be to make them a criminal offence;
	Para. 42	Calls for the following to be prohibited as criminal offences: – The generation of viable hybrid embryos with various genomes and using human DNA; – Fertilization of a human egg cell with animal sperm or the fertilization of an animal egg cell with human sperm to produce a viable embryo; – The transfer of the cell combinations or embryos referred to above to a woman; – All experiments designed to generate chimera and hybrids using human and animal genetic material;
(iii) Group of Eight (G-8)		
Communiqué, Denver Summit of the Eight, 22 June 1997	*Para. 47*	... need for appropriate domestic measures and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child.

Instrument		*Excerpts*
6. Research		
(a) Global instruments		
(i) United Nations Educational, Scientific and Cultural Organization (UNESCO)		
Universal Declaration on the Human Genome and Human Rights, 11 November 1997	*Article 13*	The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical and social implications. Public and private science policy makers also have particular responsibilities in this respect.
	Article 19 (a)	... States should seek to encourage measures enabling: (i) Assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented; ... (iii) Developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all; (iv) The free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.
(ii) United Nations Commission on Human Rights		
a. Resolution 2001/71 on human rights and bioethics, 25 April 2001	*Para. 6*	*Draws the attention* of Governments to the importance of research on the human genome and its applications for the improvement of the health of individuals and mankind as a whole, to the need to safeguard the rights of the individual and his/her dignity, as well as his/her identity and unity, and to the need to protect the confidentiality of genetic data concerning a named person;
b. Resolution 1999/63 on human rights and bioethics, 28 April 1999	*Para. 5*	*Draws the attention* of Governments to the importance of research on the human genome and its applications for the improvement of the health of individuals and mankind as a whole, to the need to safeguard the rights of the individual and his/her dignity, as well as his/her identity and unity, and to the need to protect the confidentiality of genetic data concerning a named person;

Instrument		*Excerpts*
(b) Regional instruments and documents		
(i) Council of Europe		
a. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, of 4 April 1997. (Convention on Human Rights and Biomedicine) (Council of Europe document DIR/JUR(96)14, European Treaty Series No. 164)	*Article 15*	Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.
	Article 18	1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo. 2. The creation of human embryos for research purposes is prohibited.
b. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, of 12 January 1998 (European Treaty Series No. 168)	*Second preambular para.*	Mindful of the progress that some cloning techniques themselves may bring to scientific knowledge and its medical application;
c. Council of Europe, Parliamentary Assembly, Order No. 534 (1997) on research and the cloning of human beings, of 23 September 1997, adopted by the Assembly, 1997 Ordinary Session, Fourth Part, 22-26 September 1997	*Para. 4*	The Assembly is of the opinion that work likely to lead to the cloning of humans should not be carried out.
d. Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, 2 February 1989, adopted by the Assembly, 40th Ordinary Session, 3rd Part, 30 January-3 February 1989	*Appendix, para. 3*	The human gametes employed for investigation or experimentation shall not be used to create zygotes or embryos in vitro for the purpose of procreation.
	Appendix, para. 4	... investigations of viable embryos in vitro shall only be permitted: – For applied purposes of a diagnostic nature or for preventive or therapeutic purposes; – If their non-pathological genetic heritage is not interfered with.

Instrument		*Excerpts*
	Appendix, para. 5	... research on living embryos must be prohibited, particularly: – If the embryo is viable; – If it is possible to use an animal model; – If not foreseen within the framework of projects duly presented to and authorized by the appropriate public health or scientific authority or, by delegation, to and by the relevant national multidisciplinary committee; – If not within the time limits laid down by the authorities mentioned above.
	Appendix, para. 6	... any proposed investigation which meets the above conditions [in paragraph 5] for authorization must be excluded: – Unless it is accompanied by all the required details on the embryonic material to be used, its source, foreseen time limits of implementation and the aims pursued; – Unless, on completion of the investigation, those responsible agree to inform the authorizing body of its outcome.
	Appendix, para. 14	Experiments on living embryos or fetuses, whether viable or not, shall be prohibited. Nonetheless, where a State authorizes certain experiments on non-viable fetuses or embryos only, these experiments must be undertaken in accordance with the terms of this recommendation and subject to prior authorization from the health or scientific authorities or, where applicable, the national multidisciplinary body.
	Appendix, para. 17	Genetic technology shall only be used for investigations on or with human or recombinant genetic material if appropriate authorization has been obtained. Such authorization shall be granted on the basis of the soundness of projects, full details being provided as regards their location, aims, duration and the biological material to be used; it shall be granted by the competent authorities or, by delegation, by the national multidisciplinary body.
	Appendix, para. 18	Scientific research projects on genetic engineering using genetic or recombinant genetic material shall be permitted, subject to approval: – For diagnostic purposes ... – For industrial purposes of a preventive, diagnostic or therapeutic nature ... – For therapeutic purposes ... – For purposes of scientific investigation ... – For any other purpose considered useful and beneficial to the individual and to humanity, and incorporated in projects already approved.
	Appendix, para. 19	Investigations or acts involving genetic technology shall only be authorized if [illegible] have been provided for the protection of the individual and the environment, and if they have the required qualified personnel and technical resources.

Instrument		*Excerpts*
	Appendix, para. 20	The donation of human embryological material shall be authorized solely for scientific research on diagnostic, prevention or therapeutic purposes. Its sale shall be prohibited.
e. Council of Europe, Parliamentary Assembly, Recommendation 1046 (1986) on the use of human embryos and fetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, 24 September 1986, adopted by the Assembly, 38th Ordinary Session, 2nd Part, 17-25 September 1986	*Para. 14.A*	Recommends that the Committee of Ministers: Call on the Governments of the member States: ... iii. To forbid any creation of human embryos by fertilization in vitro for the purposes of research during their life or after death;
(ii) European Union (EU)		
a. European Parliament, Resolution on human cloning, 7 September 2000 (*Bulletin of the European Union* 9-2000, Human Rights, 5/12)	*Preambular para. B*	... the undoubted need for medical research resulting from advances in knowledge of human genetics must be balanced against strict ethical and social constraints,
	Preambular para. C	... there are other ways than embryonic cloning of curing serious illnesses, such as those that involve taking stem cells from adults or from the umbilical cords of newborn babies, and other external causes of disease which require research,
	Preambular para. D	Whereas the Fifth Framework programme and Council Decision 1999/167/EC of 25 January 1999 adopting a specific programme for research, technological development and demonstration on quality of life and management of living resources (1998 to 2002) state "in the same way, no research activity understood in the sense of the term 'cloning', with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a later stage of development to the human embryo, will be supported";
	Preambular para. E	... there is a prohibition on the use of community funds, either directly or indirectly, for any such research;
	Para. 6	Reaffirms its support for biotechnological scientific research in medicine, provided that [it] is balanced against strict ethical and social constraints;
b. European Parliament, Resolution on human cloning, 15 January 1998 (1998 O.J. (C 34) 164 (15 January 1998))	*Preambular para. D*	... scientific research, which is one of the keys to human progress, must be pursued ... however, it may not undermine the dignity and integrity of the human being,
	Para. 5	Calls on the international scientific community, in carrying out research on the human genome, to refrain from the cloning of human beings;
c. European Parliament, Resolution on cloning, 12 March 1997 (1997 O.J. (C 115) 14.4.92 (12 March 1997))	*Para. 11*	Calls on researchers and doctors engaged in research on the human genome to abstain spontaneously from participating in the cloning of human beings until the entry into force of a legally binding ban;
d. European Parliament, Resolution on the ethical and legislative aspects of human cloning, 15 October 1989 (Official Journal C 96, 17.04.1989 (p. 165))	*Para. 5*	Reaffirms the principle of freedom of science and research

Instrument		*Excerpts*
	Para. 8	Regards the restraints imposed on the freedom of science and research, arising in particular from the rights of third parties and the society they constitute, as the expression in legal terms of the responsibility assumed by society as a whole for the action of the scientist and for research;
	Para. 31	Considers that the zygote also needs protection and therefore must not be subject to arbitrary experimentation ...
	Para. 37	Demands that the use of dead human embryos for therapeutic or scientific purposes be restricted in the same way as the use of human corpses;
(iii) Organization of African Unity (OAU)		
Resolution on bioethics, 32nd Assembly of OAU Heads of State and Government, July 1996 (AHG/Res. 254 (XXXII))	*Para. 3*	*Pledges* to promote within the continent the following universal rights and principles under conditions of respect for cultural, social and religious values: ... (f) Supervision of research facilities on embryos, especially those produced as a result of medical procedures offering assistance towards procreation, and the attendant application of such procedures, so as to obviate selective eugenic by-products, particularly those relating to sex considerations;
(c) Other instruments dealing with related issues		
(i) United Nations Environment Programme (UNEP)		
Convention on Biological Diversity, 1992 (United Nations, *Treaty Series*, vol. 1760, No. 30619, p. 79)	*Article 15 (7)*	Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, ... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.
(ii) United Nations General Assembly		
International Covenant on Civil and Political Rights, of 16 December 1966 (United Nations, *Treaty Series*, vol. 999, No. I-14668, p. 171, and vol. 1057, No. A-15955, p. 407)	*Article 7*	... no one shall be subjected without his free consent to medical or scientific experimentation.

Instrument		*Excerpts*
(d) Relevant documents prepared by International professional associations		
(i) World Medical Association (WMA)		
a. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, adopted in June 1964[1]	*Para. 8*	Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights ...
	Para. 10	It is the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject.
	Para. 13	The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.
	Para. 14	The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.
	Para. 15	Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
	Para. 16	Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others ...
	Para. 17	Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

[1] As amended by the 29th WMA General Assembly, Tokyo, October 1975, the 35th WMA General Assembly, Venice, Italy, October 1983, the 41st WMA General Assembly, Hong Kong, September 1989, the 48th WMA General Assembly, Somerset West, South Africa, October 1996, and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.

Instrument	*Excerpts*	
	Para. 21	The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
b. Resolution on cloning, adopted by the 147th Council Session of the World Medical Association, Paris, May 1997, and endorsed by the 49th WMA General Assembly, Hamburg, Germany, November 1997	*Para. 3*	The World Medical Association hereby calls on doctors engaged in research and other researchers to abstain voluntarily from participating in the cloning of human beings until the scientific, ethical and legal issues have been fully considered by doctors and scientists, and any necessary controls put in place.
7. Inteilectual property and commercialization aspects		
(a) Global instruments		
United Nations Educational, Scientific and Cultural Organization (UNESCO)		
Universal Declaration on the Human Genome and Human Rights, 11 November 1997	*Article 4*	The human genome in its natural state shall not give rise to financial gains.
(b) Regional instruments and documents		
(i) Council of Europe		
Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, of 4 April 1997. (Convention on Human Rights and Biomedicine) (Council of Europe document DIR/JUR(96)14, European Treaty Series No. 164)	*Article 21*	The human body and its parts shall not, as such, give rise to financial gain.
(ii) European Union (EU)		
European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989 (*Official Journal* C 96, 17/04/1989 pp. 165-171)	*Para. 38*	Insists that any commercial or industrial use of embryos or fetuses, whether it involves the production of in vitro fertilized embryos for such purposes or imports of embryos or fetuses from third countries, must be a criminal offence;
	Para. 40	Calls for trade in frozen embryos for scientific, industrial or commercial purposes to be prohibited and made a criminal offence;

Instrument		*Excerpts*
(iii) Organization of African Unity (OAU)		
a. Resolution on Bioethics, 32nd Assembly of OAU Heads of State and Government, 10 July1996 (AHG/Res. 254 (XXXII))	*Para. 3*	*Pledges* to promote within the continent the following universal rights and principles under conditions of respect for cultural, social and religious values: ... (c) Inalienability of the person, which prohibits the subjection of the human body, its components, particularly the human genes and the sequences thereof, to commercial and property rights purposes,
(c) Other instruments dealing with related issues		
(i) United Nations Environment Programme (UNEP)		
Convention on Biological Diversity, of 1992 (United Nations, *Treaty Series*, vol. 1760, No. 30619, p. 79)	*Article 16 (2)*	... In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights ...
(ii) World Trade Organization (WTO)		
Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), 15 April 1994 (Marrakesh Agreement establishing the World Trade Organization, annex 1C, United Nations, *Treaty Series*, vol. 1869, No. I-31874, p. 299)	*Article 27 (2)*	Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
	Article 27 (3)	Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; ...
(iii) Council of Europe		
Council of Europe, Parliamentary Assembly, Recommendation 1425 (1999) on biotechnology and intellectual property, 23 September 1999 (*Official Gazette* — Parliamentary Assembly — September 1999, No. VI/99 (1999))	*Para. 12*	... neither plant-, animal- nor human-derived genes, cells, tissues or organs can be considered as inventions, nor be subject to monopolies granted by patents.

Instrument		*Excerpts*
	Para. 13	... the Assembly recommends that the Committee of Ministers, in cooperation with the European Union, the World Intellectual Property Organization, the Food and Agriculture Organization of the United Nations, the World Trade Organization, the United Nations Educational, Scientific and Cultural Organization, and in accordance with the Convention on Biological Diversity: (iv) Discuss a suitable alternative system of protecting intellectual property in the field of biotechnology ... (vi) Consider the ethical aspects of the patentability of inventions involving biological and, in particular, human material.
(iv) European Union (EU)		
Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, 6 July 1998 (*Official Journal* L 213, pp. 13-21)	*Article 5*	1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. 2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. ...
	Article 6	1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation. 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: (a) Processes for cloning human beings; (b) Processes for modifying the germ line genetic identity of human beings; (c) Uses of human embryos for industrial or commercial purposes; ...
(v) European Patent Office (EPO)		
European Patent Convention, 1973 (United Nations, *Treaty Series*, vol. 1065, No. I-16208, p. 199)	*Article 53*	European patents shall not be granted in respect of: (a) Inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

Instrument		*Excerpts*
(vi) Group of Eight (G-8)		
G-8 Communiqué, Kyushu-Okinawa Summit, 2000, 23 July 2000	*Para. 63*	We recognize the need for a balanced and equitable intellectual property protection for gene-based inventions, based wherever possible on common practices and policies. We encourage further efforts in relevant international forums to achieve broad harmonization of patenting policies of biotechnological inventions.

Annex II

Selected reports and other documents

United Nations Educational, Scientific and Cultural Organization

International Bioethics Committee (IBC) report: "The Use of Embryonic Stem Cells in Therapeutic Research", Paris, 6 April 2001, document BIO-7/00/GT-1/2 (Rev.3).

Report of the Second Session of the Intergovernmental Bioethics Committee (IGBC), UNESCO, Paris, 14-16 May 2001.

Second Session of the Intergovernmental Bioethics Committee (IGBC): Report of the Director-General, document 31/C/REP/14, 17 July 2001.

Communiqué of the Round Table of Ministers of Science on "Bioethics: International Implications", UNESCO, Paris, 22-23 October 2001.

World Health Organization

"Cloning in Human Reproduction", report of the Director-General, 8 May 1997, WHO/A50/30.

Committee B, provisional summary record of the seventh meeting, 12 May 1997, WHO/A50/B/SR/7.

"Implementation of resolutions and decisions", 29 October 1997, WHO/EB/101/10.

"Implementation of resolutions and decisions", 14 January 1998, WHO/EB101/INF.DOC./3.

Provisional summary record of the sixteenth meeting, 27 January 1998, WHO/EB101/SR/16.

"Implementation of resolutions and decisions", 8 April 1998, WHO/A51/6/Add.1.

"Cloning in human health", report of the Secretariat, 1 April 1999, WHO/A52/12.

Committee A, provisional summary record of the ninth meeting, 24 May 1999, WHO/A52A/SR/9.

"Cloning in human health", report of the Director-General, 10 May 2000, WHO/A53/15.

WHO publications and documents on cloning and health issues:

"WHO Director-General condemns human cloning", 11 March 1997, press release WHO/20.

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Cloning discussion at HRP Scientific and Ethical Review Group meeting, 25 April 1997 — Technical and Ethical Aspects. The Global Response — executive summary, available upon request.

"World Health Assembly states its position on cloning in human reproduction", 14 May 1997, press release WHO/WHA/9.

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Cloning discussion at HRP Scientific and Ethical Review Group meeting, 24 October 1997. The Global Response — executive summary, available upon request.

Follow-up to recommendations of the Advisory Committee on Health Research ACHR35: "Cloning and WHO's Policies", 20-23 October 1998, WHO/ACHR36/CRP/98.7.

United Nations Commission on Human Rights

"Human rights and bioethics", report of the Secretary-General, E/CN.4/1995/74.

"Human rights and bioethics", report of the Secretary-General, E/CN.4/1997/66.

"Human rights and bioethics", report of the Secretary-General, E/CN.4/1999/90.

"Human rights and bioethics", report of the Secretary-General, E/CN.4/2001/93 and Add.1.

Subcommission on Prevention of Discrimination and Protection of Minorities

"Human rights and scientific and technological developments", Note by the Secretary-General, E/CN.4/Sub.2/1995/23.

"Potentially adverse consequences of scientific progress and its applications for the integrity, dignity and human rights of the individual", Working paper prepared by Mr. Osman El-Hajjé, E/CN.4/Sub.2/1997/34.

Working Group on Indigenous Populations, "Human genome diversity research and indigenous peoples", Note by the Secretariat, E/CN.4/Sub.2/AC.4/1998/4 and Add.1.

European Union

The Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) to the European Commission, Opinion No. 8, "Ethical Aspects of Patenting Inventions Involving Elements of Human Origin", 25 September 1996.

The Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) to the European Commission, Opinion No. 9, "Ethical Aspects of Cloning Techniques", 28 May 1997.

The European Group on Ethics in Science and New Technologies (EGE) to the European Commission, Opinion No. 12, "Ethical Aspects of Research Involving the Use of Human Embryos in the context of the 5th Framework Programme", 23 November 1998.

Organization of American States

Draft Legislative Guide on Medically assisted Fertility, OAS/Ser. Q, CJI/Res.18 (LVII-O/00), 19 August 2000.